

EXHIBIT 7

From: Chen, Meng [ETHUS] <MChen28@its.jnj.com>
Sent: Thu, 29 Jan 2009 18:28:50 GMT
To: Lisa, Bryan [ETHUS] <BLisa@its.jnj.com>
Subject: FW: TVT IFUs on tape extrusion, exposure and erosion

Pardon me again, from what I see each day, these patient experiences are not "transitory" at all.

-----Original Message-----

From: Chen, Meng [ETHUS]
Sent: Thursday, January 29, 2009 12:39 PM
To: Lisa, Bryan [ETHUS]
Subject: TVT IFUs on tape extrusion, exposure and erosion

Bryan: I have re-checked all three IFUs (for TVT-A, TVT-O and TVT-S). Everyone has the language "Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation." First, I was wrong before. There is such language in every one. But it should be spelled out that Transitory local irritation at the wound site and a transitory foreign body response to the tape may occur. This response could result in tape extrusion, tape erosion, fistula formation or inflammation. Furthermore, in light of the recent burst of reports and the FDA public health advisory, I am not sure a very general statement like the above and list such as second one in the Adverse Reactions are still sufficient. Anyway, I just want to share my sense of change in tone in the regulatory agency inquiries. Thanks, Meng

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